DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 27, 2015

WestTec, LLC
Mr. John Jensen
265 North Main Street
Ste. D-115
Kaysville, Utah 84037

Re: K141085
Trade/Device Name: WestTec Procedure Facemask
WestTec Surgical Facemask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: February, 2015
Received: February 25, 2015

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141085

Device Name
WestTec Procedure Facemask
WestTec Surgical Facemask

Indications for Use *(Describe)*
WestTec Procedure and Surgical facemasks are intended to be worn by healthcare workers to protect the user and patient against transfer of microorganisms, blood and body fluids, and airborne particulates. The WestTec Procedure and Surgical facemasks are single use, disposable devices provided non-sterile.

Facemask Name	Model Number	Color
Procedure	10-1318	Blue
	10-1358	White
Surgical	20-1318	Blue
	20-1358	White

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K141085

Summary Preparation Date: **Original submission;** July 2014
Revision Submission: February 2015
Revision Submission: March 26, 2015

510(k) Submitter:
John Jensen
WestTec LLC.
265 North Main Street
Ste. D-115
Kaysville, Utah 84037
Phone: 435-200-4608
E-mail: jjensen@westtec.us

Device Trade Names: WestTec Procedure Facemask
WestTec Surgical Facemask

Device Common Name: Surgical Mask

Classification Name: Surgical apparel
Device Classification Class II per 21 CFR 878.4040
Product Code FXX

Predicate Devices:

The WestTec Procedure and Surgical facemasks, the subject of this submission, are substantially equivalent to the Jingzhou Haixin Green Cross Medical Products Co., Ltd Surgical Mask (K123787).

Device Description:

The WestTec Procedure and Surgical facemasks are identical with the exception that the Surgical Mask has a Comfort Band to keep the inner layer away from the user's mouth to provide space between the users face and the mask making it more comfortable to wear. Both facemasks are manufactured with three layers of nonwoven polypropylene materials. The facemasks are held in place over the user's mouth and nose by two elastic ear loops welded to each facemask. The elastic ear loops are not made with natural rubber latex. The facemasks have a malleable Nose Band contained in the layers of the facemask to allow the user to fit the facemask around their nose. The facemasks are sold non-sterile and are intended to be a single use, disposable device.

Intended Use:

WestTec Procedure and Surgical facemasks are intended to be worn by healthcare workers to protect the user and patient against transfer of microorganisms, blood and body fluids, and airborne particulates. The WestTec Procedure and Surgical facemasks are single use, disposable devices provided non-sterile.

Facemask Name	Model Number	Color
Procedure	10-1318	Blue
	10-1358	White
Surgical	20-1318	Blue
	20-1358	White

Technological Characteristics and Similarities of the Device and the Predicate:

The WestTec Procedure and Surgical facemasks are substantially equivalent to the predicate device, Jingzhou Haixin Green Cross Medical Products (K123787), with regard to the intended use and technological characteristics. The WestTec facemasks and the Jingzhou Haixin Green Cross Medical Products mask use polypropylene coverstock materials of similar size to encase a similar sized polypropylene filter layer. Both facemasks use a malleable nose band to fit the mask to the users face and utilize similar sized ear loops to secure the facemask to the users face. Any technological differences are not expected to affect safety or performance of the device.

Comparison of Intended Use, Design, Material, and Specifications

Description	WestTec Masks	Predicate Device (K123787)
Indication for Use:	WestTec Procedure and Surgical facemasks are intended to be worn by healthcare workers to protect the user and patient against transfer of microorganisms, blood and body fluids, and airborne particulates. The WestTec Procedure and Surgical facemasks are single use, disposable devices provided non-sterile.	Nose and mouth covering for health care workers and patients to prevent microorganism, body fluid, and particulate aerosol transfer.
Layers	Three	Three

Description	WestTec Masks	Predicate Device (K123787)
Materials	Outer Layer is 100% spunbond polypropylene. Middle Layer is 100% meltblown polypropylene filter media. Inner Layer is 100% spunbond polypropylene. Earloops are soft non natural rubber latex, elastic loops. Nose Band is two 0.018" diameter steel wires encased in polyethylene The Surgical Mask includes a	Outer Layer is 100% spunbond polypropylene. Middle Layer is 100% meltblown polypropylene filter media. Inner Layer is 100% spunbond polypropylene. Earloops are soft non natural rubber latex, elastic loops. Nose Band is plastic wire
Dimensions	6.875" x 3.75" (175mm x 95mm)	175mm x 90mm
Mask Style	Flat pleated	Flat pleated
Design	Ear Loop	Ear Loop
Color	Blue, White	White

Comparison of Device Performance

The following table compares the results of testing performed on the WestTec masks to the published results of the predicate device. Since both the WestTec and the predicate facemasks are labeled to meet the ASTM F2100 *Standard Specification for Performance of Materials Used in Medical Face Masks* requirements for Level 2 performance classification, these requirements are also shown in the table.

Description	WestTec Masks	Predicate Device (K123787)	ASTM F2100 Requirement for Level 2 Classification
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120mmHg	29 out of 32 pass at 120mmHg	29 out of 32 pass at 120mmHg
Particulate Filtration Efficiency ASTM F2299	98.0%	99.1%	≥98%
Bacterial Filtration Efficiency ASTM F2101	99.7%	99.8%	≥98%

Description	WestTec Masks	Predicate Device (K123787)	ASTM F2100 Requirement for Level 2 Classification
Differential Pressure (Delta P) MIL-M-36954C	3.3 – 3.6 mmH_2O/cm^2	2.6 – 2.9 mmH_2O/cm^2	<5.0 mmH_2O/cm^2
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1 Non Flammable	Class 1
Biocompatibility ISO 10993-5, -10	Biocompatible	Biocompatible	

Discussion of Non-Clinical Tests Performed to Determine Substantial Equivalence

The non-clinical tests listed in the above table were performed to determine substantial equivalence. Tests were conducted following the recommended procedures outlined in the following standards. Test results met all relevant requirements in the test standards, and are comparable to the predicate device.

- ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask, disposable
- 16 CFR Part 1610 Standard For The Flammability Of Clothing Textiles
- ISO 10993-5 & -10 Biological evaluation of medical devices

Test results show the WestTec facemasks met all relevant requirements of the above test standards. The results also indicate the WestTec facemasks have similar results as the predicate and both meet the ASTM F2100 requirements for a Class 2 Performance Level facemask. More details of non-clinical tests are summarized in Tab 18.

Discussion of Clinical Tests Performed

Not applicable

Conclusions:

The WestTec facemasks and the predicate facemask are similar in size and are made of similar materials, polypropylene coverstocks to encase a polypropylene filter layer. Both the WestTec facemasks and the predicate facemask have the same intended use. Bench testing detailed in this submission demonstrates the WestTec facemasks and the predicate facemask have similar functional characteristics. The technological characteristics do not raise any new questions of safety or effectiveness. Therefore, the WestTec facemasks are substantially equivalent to the predicate device.